Non-Confidential Summary of Safety and Effectiveness

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22-Feb-08

JUN 23 2008

RemGenic LLC
3734 Lincoln Place Dr.
Des Moines, IA 50312

Tel - 515-339-7722

Official Contact: Russell Bird

Proprietary or Trade Name: LaminAir CPAP nasal mask

Common/Usual Name: Patient interface for use with CPAP systems

Classification Name: Ventilator, non-continuous (respirator), accessory
BZD – 868.5905

Device: CPAP nasal mask with pillows

Predicate Devices: InnoMed – Nasal Aire K022465

Device Description:

The proposed nasal patient interface incorporates a number of features, which are designed to maximize seal and comfort, and maintain the mask in the correct position throughout use.

- Three (3) sizes of nasal inserts to assure a good fit
- Integral fixed leak port
- Headgear for attachment

Indications for Use: A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and / or ventilatory support. Single patient, multi-use and Multi-patient, multi-use

Patient Population: Adults with OSA

Environment of Use: Hospitals, Home, sub-acute care settings, sleep labs

Contraindications: None

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Comparative table:

Features	Predicate InnoMed Nasal Aire K022465	Proposed Device
Indications for use	An accessory to positive pressure ventilation devices for patients suffering from OSA requiring positive pressure breathing therapy (i.e. CPAP, bi-level)	A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and / or ventilatory support.
Environment of Use	Home, Hospital, Sub-acute Institutions, Sleep labs	Same
Patient Population	Adult	Same
Contraindications	None	None
Single patient, multi use **Multi-patient, multi-use**	Yes under K022465 clearance	Yes
Multiple sizes of nasal cushions	Yes - five	Yes - three
Components	Headgear Nasal prongs Tubing Connector	Headgear Nasal prongs Tubing Connectors
Dead space	Nasal pieces – 5 to 18 ml	Nasal piece - largest 23 ml
Fixed leak port	Yes	Yes
Materials	Polypropylene PVC tubing Silicone	Polypropylene PVC tubing Silicone

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is viewed as substantially equivalent to the predicate device, K022465.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2008

RemGenic LLC
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K080516
Trade/Device Name: LaminAir CPAP Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 13, 2008
Received: May 14, 2008

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

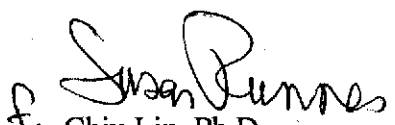
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K080516

Device Name: LaminAir CPAP nasal mask

Indications for Use: A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and / or ventilatory support.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080516